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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,347	08/19/2004	Jeffrey S Kiel	455-020	7386

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,347	KIEL ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-16,19,20 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18,21,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Applicant's election of Group III (claims 17, 18, 21, 26 & 27) in the reply filed on 04/18/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Acknowledgement is also made of the Information Disclosure Statement (IDS) filed 01/18/05.

Claims 1-16, 19, 20 and 22-25 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-27 are pending in this action. Claims 1-16, 19, 20 and 22-25 have been withdrawn. Claims 17, 18, 21, 26 and 27 are being examined in this action. Claims 17, 18, 21, 26 and 27 are rejected.

Claim Objections

Claim 18 is objected to because of the following informalities:

The limitation "selected from a group consisting of" should instead be recited as "selected from *the* group consisting of" to place the claim in proper Markush terminology. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, the limitation "further including at least one…" renders the claim indefinite as it is unclear as to what additional components are contained asides from those instantly recited. It is suggested that the limitation be recited as "further *comprising* at least one...".

Claims 26 and 27 are indefinite based on the term "substantial absence". It is unclear as to what this term entails. A review of the instant specification does not clearly set forth a definition for the term 'substantial absence'. Is the "substantial absence of other active ingredients" based on substantial absence in terms of weight, percentage, volume or size?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 18, 21, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopdekar *et al.* (hereinafter "Chopdekar") (U.S. Pat. No. 5,663,415).

Chopdekar ('415) teaches a process for preparing pure antihistamine tannate compositions comprising (a) contacting an antihistamine in the form of its free base with tannic acid in the presence of water at a maximum temperature which will not cause decomposition of the antihistamine tannate to an extent of greater than about 5 wt% based on the weight of the antihistamine tannate; (b) allowing the antihistamine to remain in contact with the tannic acid in the presence of water; and (c) freeze-drying the antihistamine tannate resulting from step (b) (see Abstract and column 1, lines 5-10); (col. 2, lines 20-38).

When the antihistamine is present as the salt (i.e., the hydrochloride), it is dissolved in cold water and neutralized with a stoichiometric amount of a base. The antihistamine free base precipitates out, recovered by filtration, washed with cold water and air-dried. The pure antihistamine tannate composition is administered in the form of a suspension (see reference column 2, lines 8-45).

The antihistaminic tannate compositions of Chopdekar have a high level of purity (col. 1, lines 5-10). Chopdekar teaches that antihistaminic compounds are provided in the form of their free bases and salts, e.g., hydrochloride, maleate and *tannate.* According to Chopekar, it is desirable to utilize the antihistamine in the form of its *tannate* salt, because such salt is generally quite stable and may be administered in such form without unwanted side effects (col. 13-23).

The antihistamine to be reacted with the tannic acid can be diphenhydramine (col. 3, lines 1-10); Claim 2. The pure antihistamine tannate compositions can be administered in solid form, i.e., a pill (col. 2, lines 8-16).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Chopdekar. Chopdekar teaches processes for preparing pure antihistaminic tannate compositions whereby tannic compounds are provided in the form of their salts, such as *tannate* salt and whereby the tannate salt is preferred because it is a stable salt that can be administered in such form without unwanted side effects. Since the compositions employ the same active ingredient as claimed by Applicant, it is expected that the compositions of Chopdekar would also be highly effective for the treatment of upper respiratory conditions as instantly desired by Applicant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 18, 21, 26 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 18, 21, 26 and 27 of copending Application No. 10/505,355 ('355 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '355 copending application also claims a therapeutic composition for the symptomatic treatment of respiratory allergies in a warm-blooded animal, comprising a pharmaceutically effective amount of diphenhydramine tannate prepared by (a) dissolving the salt or free base of diphenhydramine in a pharmaceutically acceptable liquid to form a solution; (b) separately adding a dispersing agent with tannic acid to formulate a dispersion; (c) combining the solution from step (a) with step (b) to form a diphenhydramine salt and (d) combining the tannate salt of diphenhydramine with a pharmaceutically acceptable excipient to form a therapeutic dosage form. The '347 application

includes an additional step (e) that provides for the processing of the granulate into a tablet, capsule or other dosage form. However, note that the last processing step of the '355 application also yields a therapeutic dosage form.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Pertinent Art

Prior art made of record and deemed relevant by Examiner:

- Sunshine *et al.* - (U.S. Pat. No. 5,025,019)
- Frisbee *et al.* - (U.S. Pat. No. 6,013,280)

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

hns

June 23, 2008